

Docket Number: 037003-0275739

Client Reference: 1997-30-0565D1

PATENT APPLICATION



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re The Application of REFF et al.

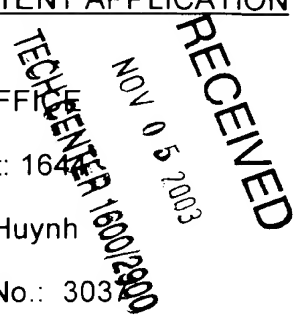
Group Art Unit: 164

Application No.: 09/292,053

Examiner: P. Huynh

Filed: April 14, 1999

Confirmation No.: 303



For: GAMMA-1 ANTI-HUMAN CD23 MONOCLONAL ANTIBODIES AND USE
THEREOF AS THERAPEUTICS

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR 1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. The attached references were cited in U.S. and international/foreign patent applications related to the present application. It is respectfully requested that the listed references be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue there from.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.

Please charge Deposit Account 033975 in the amount of \$180.00 in payment of the fee under 37 CFR 1.17(p). Please credit or debit Deposit Account 033975 as needed to ensure consideration of the disclosed information.

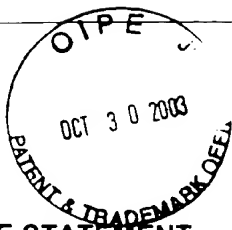
Respectfully Submitted,

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FORM PTO-1449 (modified)
To: U.S. Department of Commerce
(PW FORM PAT-1449)
Patent and Trademark Office



Atty. Dkt. No.	M#	Client Ref.
	0275739	1997-30-0565D1

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Applicant: REFF <i>et al.</i>	
Appln. No.: 09/292,053	
Filing Date: April 14, 1999	
Examiner: P. Huynh	Group Art Unit: 1644

Date: October 30, 2003 Page 1 of 4

U.S. PATENT DOCUMENTS

Examiner's Initials*		Document Number	Date MM/YYYY	Name (Family Name of First Inventor)	Class	Sub Class	Filing Date
	AR	4,975,369	12/1990	Beavers et al.			
	BR	5,348,876	09/1994	Michaelson et al.			
	CR	5,543,144	08/1996	Chang et al.			
	DR	5,585,089	12/1996	Queen et al.			
	ER	5,648,260	07/1997	Winter et al.			
	FR	5,648,267	07/1997	Reff			
	GR	5,658,570	08/1997	Newman et al.			
	HR	5,811,524	09/1998	Brams et al.			
	IR	6,011,138	01/2000	Reff et al.			
	JR	6,635,600	06/1997	Fanger et al.			

FOREIGN PATENT DOCUMENTS

						English Abstract	Translation Readily Available
		Document Number	Date MM/YYYY	Country	Inventor Name	ENCLOSED N O	ENCLOSED N O
	KR	WO 96/12741	05/1996	WIPO	Glaxo Group Ltd.		
	LR	WO 96/12742	05/1996	WIPO	Glaxo Group Ltd.		
	MR	WO 89/00138	01/1989	WIPO	Gunnar Strömberg		
	NR	WO 92/17207	10/1992	WIPO	Tanox Biosystems Inc.		
	OR	WO 93/02108	02/1993	WIPO	IDEC Pharmaceuticals Inc.		
	PR	WO 88/06891	09/1988	WIPO	Aktiebolaget Astra		
	QR	WO 87/07302	12/1987	WIPO	Laboratoires Unicet		

OTHER

	RR	Rector et al., "Detection and characterization of monoclonal antibodies specific to IgE receptors on human lymphocytes by flow cytometry", <i>Immunol.</i> , 55: 481-488 (1985).
	SR	Suemura et al., "Monoclonal anti-Fc epsilon receptor antibodies with different specificities and studies on the expression of Fc epsilon receptors on human B and T cells", <i>J. Immunol.</i> , 137: 1214-1220 (1986).
	TR	Noro et al., "Monoclonal antibody (H107) inhibiting IgE binding to Fc epsilon R(+) human lymphocytes", <i>J. Immunol.</i> , 137: 1258-1263 (1986).
	UR	Yu et al., "Negative feedback regulation of IgE synthesis by murine CD23", <i>Nature</i> 369: 753-756 (1994).
	VR	Bonnefoy et al., "Regulation of IgE synthesis by CD23/CD21 interaction", <i>Int. Arch. Allergy Immunol.</i> , 107:40-42 (1995).
	WR	Grosjean et al., "CD23/CD21 interaction is required for presentation of soluble protein antigen by lymphoblastoid B cell lines to specific CD4+ T cell clones", <i>Eur. J. Immunol.</i> , 24: 2982-2988 (1994).
	XR	Pene et al., "Interleukin 5 enhances interleukin 4-induced IgE production by normal human B cells. The role of soluble CD23 antigen", <i>Eur J. Immunol.</i> , 18: 929-935 (1988).
	YR	Saxon et al., "Soluble CD23 containing B cell supernatants induce IgE from peripheral blood B-lymphocytes and costimulate with interleukin-4 in induction of IgE", <i>J. Allergy Clin. Immunol.</i> , 86 (3 pt 1) 333-344 (1990).
	ZR	Hassner and Saxon, "Isotype-specific human suppressor T cells for IgE synthesis activated by IgE-anti-IgE immune complexes", <i>J. Immunol.</i> , 132: 2844 (1984).

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Date:	Page	Applicant:	Appln. No.:
OTHER (Continued)		October 30, 2003	2 of 4	REFF et al.	09/292,053
		Client Ref. No.:	Atty. Dkt. No.:	Examiner:	Group Art Unit:
		1997-30-0565D1	037003-0275739	P. Huynh	1644
AAR	Carroll et al., "Mouse x human heterohybridomas as fusion partners with human B cell tumors", J. Immunol. Methods, 89: 61 (1986).				
BBR	Boerner et al., "Production of antigen-specific human monoclonal antibodies from in vitro-primed human splenocytes", J. Immunol., 147: 86 (1991).				
CCR	Luo et al., "Cross-linking of CD23 antigen by its natural ligand (IgE) or by anti-CD23 antibody prevents B lymphocyte proliferation and differentiation" J. Immunol., 146(7):2122-9 (1991).				
DDR	Groves et al., "Production of an ovine monoclonal antibody to testosterone by an interspecies fusion", Hybridoma, vol. 6(1):71 (1987).				
EER	Robbins, "Diseases of Immunity," Pathologic Basis of Disease, pp. 197-199 (1994).				
FFR	Seaver, "Monoclonal Antibodies in Industry: More Difficult than Oringally Thought," Genetic Engineering, 14(14): 10 and 21 (1994).				
GGR	Haak-Frendscho et al., "Administration of an anti-IgE antibody inhibits CD23 expression and IgE production in vivo", Immunology, 82:306 (1994).				
HHR	Delespesse et al., "Human IgE-binding factors", Immunology Today, 10:159, (1989).				
IIR	Durum and Oppenheim, "Proinflammatory Cytokines and Immunity," Fundamental Immunology, 3rd Edition, Chapter 21, p. 801-835, Raven Press Ltd. (1993).				
JJR	Vercelli et al., "Induction of human IgE synthesis requires interleukin 4 and T/B cell interactions involving the T cell receptor/CD3 complex and MHC class II antigens", J. Exp. Med., 169:1295 (Apr. 1989).				
KKR	Presta et al., "Humanization of an antibody directed against IgE", J. Immunology, 151(5):2623 (Sep. 1993).				
LLR	Strike et al., "Production of human-human hybridomas secreting antibody to sheep erythrocytes after in vitro immunization", J. Immunol., 132(4): 1798 (Apr. 1984).				
MMR	Cruse et al., Illustrated Dictionary of Immunology, CRC Press, p. 69 (1995).				
NNR	Capon et al., "Designing CD4 immunoadhesins for AIDS therapy", Nature, 337:525 (Feb. 1989).				
OOR	Bourget et al., Eur. J. Immunol., 12(7):1872-76 (1995).				
PPR	Bonnefoy et al., "A new role for CD23 in inflammation", Immunol. Today, 17(9): 418-20 (1996).				
QQR	Urlaub et al., Somatic Cell and Mol. Genetics, 12(6):555-66 (1986)				
RRR	Co et al., "Humanized anti-Lewis Y antibodies: in vitro properties and pharmacokinetics in rhesus monkeys", Can. Res., 56:1118-25 (1996).				
SSR	Ono et al., "Deletion of SHIP or SHP-1 reveals two distinct pathways for inhibitory signaling", Cell, 90:293-301 (1997).				
TTR	Parren et al., "Characterization of IgG FcR-mediated proliferation of human T cells induced by mouse and human anti-CD3 monoclonal antibodies. Identification of a functional polymorphism to human IgG2 anti-CD3", J. Immunol., 148(3):695-701 (1992).				
UUR	Steplewski et al., "Biological activity of human-mouse IgG1, IgG2, IgG3, and IgG4 chimeric monoclonal antibodies with antitumor specificity", Proc. Natl. Acad. Sci., 85(13):4852-4856 (1988).				
VVR	Lund et al., "Human Fc gamma RI and Fc gamma RII interact with distinct but overlapping sites on human IgG", J. Immunol., 147(8):2657-2662 (1991).				
WWR	Co et al., "Chimeric and humanized antibodies with specificity for the CD33 antigen", J. Immunol., 148(3):1149-1154 (1992).				
XXR	Shakib et al., "A study of the interrelationship between circulating IgG subclass anti-IgE autoantibodies, IgE and soluble CD23 in asthma", Allergol. Immunopathol., 21(1):20-24 (1993).				
YYR	Spiegelberg et al., "Fc receptors for IgE and interleukin-4 induced IgE and IgG4 secretion", J. Invest. Dermatol., 94(6):49S-52S (1990).				
ZZR	Maliszewski et al., "Induction of B cell activities by interleukin 4 is inhibited by a receptor-specific monoclonal antibody in vitro", Eur. J. Immunol., 20:1735-1740 (1990).				
AAAR	Yanagihara et al., "Suppression of IgE production by IPD-1151T (suplatast tosilate), a new dimethylsulfonium agent: (1). Regulation of murine IgE response", Jpn J. Pharmacol., 61:23-30 (1993).				
BBBR	Hjultström et al., "No role of interleukin-4 in CD23/IgE-mediated enhancement of the murine antibody response in vivo", Eur. J. Immunol., 25:1469-1472 (1995).				
CCCR	Escura et al., Immunol., 86:343-350 (1995).				
DDDR	Gustavsson et al., "CD23/IgE-mediated regulation of the specific antibody response in vivo", J. Immunol., 152(10):4793-4800 (1994).				

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Date: October 30, 2003	Page 3 of 4	Applicant: REFF et al.	Appln. No.: 09/292,053
OTHER (Continued)		Client Ref. No.: 1997-30-0565D1	Atty. Dkt. No.: 037003-0275739	Examiner: P. Huynh	Group Art Unit: 1644
EEER	Yanagihara et al., "Establishment of a sensitive radioimmunoassay for the detection of human IgE-binding factor (soluble CD23)", Int. Arch. Allergy Immunol., 98:189-199 (1992).				
FFFR	Bonnefoy et al., "Receptors for IgE", Curr. Opin in Immunol., 5:944-9 (1993).				
GGGR	Burton et al., "Human antibody effector function", Adv. Immunol., 51:1-84 (1992).				
HHHR	Paul et al., Fundamental Immunology, 705 & 870 (1994).				
IIIR	Webster's II New Riverside University Dictionary, Houghton-Mifflin Co., Boston, p. 933 (1984).				
JJJR	Van Noort et al., "Cell Biology of Autoimmune Diseases," Intl. Rev. of Cytology, 178:127-205 (1998).				
KKKR	Abaza et al., "Effects of Amino Acid Substitutions Outside an Antigenic...", J. Prot. Chem., 11(5):433-444 (1992).				
LLLR	Plater-Zyberk et al., "Marked amelioration of established collagen-induced arthritis by treatment with antibodies to CD23 in vivo", Nature Medicine, 1(8):781-785 (1995).				
MMMR	Skolnick et al., "From genes to protein structure and function: novel applications of computational approaches in the genomic era", TIBTECH, 18:34-9 (2000).				
NNNR	The Merck Manual of Diagnosis and Therapy, 17 th Edition, Beers et al., eds., Whitehouse Station, NJ, pp. 416-422 (1999).				
OOOR	Busse et al., J. of allergy and Clinical Immunol., 107(2):abstract no. 354 (Feb. 2001).				
PPPR	Nakamura et al., "In vitro IgE inhibition in B cells by anti-CD23 monoclonal antibodies is functionally dependent on the immunoglobulin Fc domain", Intl. J. of Immunopharmacol., 22:131-41 (2000).				
QQQR	Yoshikawa et al., "Soluble Fc epsilon RII/CD23 in patients with autoimmune diseases and Epstein-Barr virus-related disorders: analysis by ELISA for soluble Fc epsilon RII/CD23", Immunomethods, 4(1):65-71 (Feb. 1994).				
RRRR	Muino et al., "The importance of specific IgG and IgE autoantibodies to retinal S antigen, total serum IgE, and sCD23 levels in autoimmune and infectious uveitis", J. clin. Immunol., 19(4):215-222 (Jul. 1999).				
SSSR	Soh et al., "IgE and its related phenomena in bullous pemphigoid", Br. J. Dermatol. 128(4):371-377 (Apr. 1993).				
TTTR	Fries et al., "Monocyte receptors for the Fc portion of IgG studies with monomeric human IgG1: normal in vitro expression of Fc gamma receptors in HLA-B8/Drw3 subjects with defective Fc gamma-mediated in vivo clearance", J. Immunol., 129: 1041-1049 (1982).				
UUUR	Kurlander and Batker et al., "The binding of human immunoglobulin G1 monomer and small, covalently cross-linked polymers of immunoglobulin G1 to human peripheral blood monocytes and polymorphonuclear leukocytes", J. Clin. Invest., 69: 1-8 (1982).				
VVVR	Woof, "The monocyte binding domain(s) on human immunoglobulin G", Mol. Immunol., 21:523-527 (1984).				
WWWR	Karas et al., "Characterization of the IgG-Fc receptor on human platelets", Blood, 60:1277-1282 (1982).				
XXXR	Van de Winkel and Anderson, "Biology of human immunoglobulin G Fc receptors", J. Leuk. Biol., 49:511-524 (1991).				
YYYY	Huizinga et al., "Binding characteristics of dimeric IgG subclass complexes to human neutrophils", J. Immunol., 142:2359-2364 (1989).				
ZZZR	Bosma et al., "A severe combined immunodeficiency mutation in the mouse", Nature, 301:527 (1983).				
AAAAR	Mosier et al., "Transfer of a functional human immune system to mice with severe combined immunodeficiency", Nature, 335:256 (1988).				
BBBBR	Mosier et al., "Immunodeficient mice xenografted with human lymphoid cells: new models for in vivo studies of human immunobiology and infectious diseases", J Clin Immunol., 10:185-91 (1990).				
CCCCR	Abedi et al., "Immunoglobulin production in severe combined immunodeficient (SCID) mice reconstituted with human peripheral blood mononuclear cells", Eur. J. Immunol., 22:823 (1992).				
DDDDR	Mazingue et al., "Obtention of a human primary humoral response against schistosome protective antigens in severe combined immunodeficiency mice after the transfer of human peripheral blood mononuclear cells", Eur. J. Immunol., 21:1763 (1991).				

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Date: October 30, 2003	Page 4 of 4	Applicant: REFF et al.	Appln. No.: 09/292,053
OTHER (Continued)		Client Ref. No.: 997-30-0565D1	Atty. Dkt. No.: 037003-0275739	Examiner: P. Huynh	Group Art Unit: 1644
AR	Kirchherr et al., "Regulation of human IgE response in hu-PBL-SCID mice", Cellular Immunology, 151:241 (1993).				
BR	Spiegelberg et al., "Role of interleukin-4 in human immunoglobulin E formation in hu-PBL-SCID mice", J. Clin. Invest., 93:711 (1994).				
CR	Carballido et al., "IL-4 induces human B cell maturation and IgE synthesis in SCID-hu mice. Inhibition of ongoing IgE production by in vivo treatment with an IL-4/IL-13 receptor antagonist", J. Immunol., 155:4162 (1995).				
DR	King et al., "Expression, purification and characterization of a mouse-human chimeric antibody and chimeric Fab' fragment", Biochem J., 281:317-23 (1992).				
ER	Queen et al., "A humanized antibody that binds to the interleukin 2 receptor", Proc. Nat. Acad. Sci. USA, 86:10029 (1989).				
FR	Love et al., "Recombinant antibodies possessing novel effector functions", Methods Enzymol., 178:515-27 (1989).				
GR	Hutzell et al., "Generation and characterization of a recombinant/chimeric B72.3 (human gamma 1)", Cancer Res., 51:181 (1991).				
HR	Chiang et al., "Direct cDNA cloning of the rearranged immunoglobulin variable region", Biotechniques, 7(4):360-6 (1989).				
IR	Heinrich et al., "Characterization of a human T cell-specific chimeric antibody (CD7) with human constant and mouse variable regions", J. Immunol., 143:3589 (1989).				
JR	Hardman et al., "Generation of a recombinant mouse-human chimaeric monoclonal antibody directed against human carcinoembryonic antigen", Int. J. Cancer, 44:424 (1989).				
KR	Orlandi et al., "Cloning immunoglobulin variable domains for expression by the polymerase chain reaction", Proc. Nat. Acad. Sci. USA, 86(10):3833-7 (1989).				
LR	Norman et al., "Reversal of Acute Allograft Rejection With Monoclonal Antibody", Transpl. Proc., 17:39-41 (1985).				
MR	Sarfati et al., "Elevation of IgE-binding factors in serum of patients with B cell-derived chronic lymphocytic leukemia", Blood, 71:94-98 (1988).				
NR	Saragovi et al., "Design and synthesis of a mimetic from an antibody complementarity-determining region", Science, 16:253(5021):792-5.				
Examiner			Date Considered:		
<p>*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.</p>					

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